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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SACV11-00734 CJC MLGx

MICHAEL RUHE, and VICENTE CATALA,

Plaintiffs,

vs.

MASIMO CORPORATION, and DOES 1 to 100, inclusive,

Defendants.

Case No.:

COMPLAINT FOR: (1) CONSTRUCTIVE DISCHARGE IN VIOLATION OF THE DODD-FRANK WALL STREET REFORM AND CONSUMER PROTECTION ACT OF 2010, 15 U.S.C. §78u-6(h); (2) CONSTRUCTIVE DISCHARGE IN VIOLATION OF PUBLIC POLICY; (3) UNFAIR COMPETITION (BUSINESS & PROFESSIONS CODE SECTION 17200); (4) DECLARATORY RELIEF REGARDING VALIDITY OF ARBITRATION AGREEMENTS

DEMAND FOR JURY TRIAL

Plaintiffs MICHAEL RUHE and VICENTE CATALA (hereinafter "RUHE" and "CATALA," and collectively, "Plaintiffs") bring this action against Defendant MASIMO CORPORATION (hereinafter "MASIMO"), and Does 1 to 100, inclusive, for damages resulting from Defendants' unlawful conduct, and therefore allege as follows:

INTRODUCTION

Plaintiffs are medical device sales representatives (known as "Territory Managers" or

"TMs") who used to work for Defendant MASIMO. In October 2010, Plaintiffs RUHE and CATALA were compelled to resign their employment with MASIMO because MASIMO engaged in illegal activity, including but not limited to:

(a) pressuring TMs to sell medical devices that MASIMO and the TMs knew to be defective, and to deceive physicians about the devices' lack of accuracy and other problems;

(b) repeatedly threatening and harassing TMs who raised issues about misrepresentations and improper sales tactics, by stating, for example, that they needed to either "get on board" or quit their jobs;

(c) berating and criticizing TMs who reported device inaccuracies and malfunctions;

(d) violating public policies applicable to medical device TMs;

(e) participating in rigged clinical studies designed by MASIMO to exclude results outside of MASIMO's claimed accuracy specifications for the devices, and only reporting results within the accuracy specifications;

(f) obtaining patients' private health information from the patients' physicians for MASIMO's own use, without patient knowledge or consent; and

(g) hiding a self-imposed recall on one of its devices from the United States Food & Drug Administration ("FDA").

MASIMO is a publicly traded medical device manufacturer whose pulse oximetry devices are known throughout the medical industry as the "gold standard" for measuring oxygen saturation in hemoglobin (a protein in the blood that carries oxygen from the lungs to body tissues, and carbon dioxide from those tissues back to the lungs). Not all of MASIMO's medical devices enjoy "gold standard" status within the medical industry, however.

MASIMO's apparent "next big thing," as evidenced by its aggressive marketing and investment in sales personnel, as well as by the dominant position the new product line occupies on MASIMO's website home page, is its technology for non-invasive measurement of hemoglobin levels in a patient's blood. The hemoglobin measurement is a frequently ordered test in hospitals, emergency rooms, surgical centers, physicians' offices (especially family

practitioners, pediatricians, and OB/GYNs), and nephrology clinics. It is reimbursed by government programs such as Medicare and by many private insurance plans.

The biggest "sticking point" – literally – when ordering a hemoglobin test is the fact that the patient needs to have blood drawn with a needle. While this is usually not a major problem for a patient who needs a hemoglobin test, it can be painful and the lab results take time to process. MASIMO's non-invasive hemoglobin devices were conceived to eliminate these problems by reading a patient's hemoglobin level using a finger sensor that projects red and infrared light through a patient's skin, providing a result in under a minute. The idea of a non-invasive method for measuring hemoglobin is especially attractive to pediatricians, whose infant and toddler patients (and oftentimes their parents) have an aversion to needles, and to medical practices where patients are having hemoglobin levels checked frequently.

MASIMO has been in a race with other medical device manufacturers to be the first to bring to market a non-invasive hemoglobin spot checking device (i.e., a device that takes a single reading after measuring hemoglobin levels for 45-90 seconds). In May 2008, MASIMO obtained FDA approval for the *Radical-7*, a device that measures total hemoglobin (designated by the MASIMO trademark "SpHb"), pulse oximetry (designated as "SpO2"), pulse rate, perfusion index, and other measurements on a continuous basis (multiple readings over a period of time, such as during or after a surgical procedure to monitor blood loss or to detect internal bleeding post-surgery).

MASIMO used its FDA approval of the Radical-7 to obtain speedy FDA approval of its hemoglobin spot checking devices, including the *RadCheck* in October 2008 and the *Pronto* in July 2009. To obtain this approval, MASIMO represented to the FDA that the RadCheck and the Pronto were "substantially equivalent" to the predicate device, meaning that it was "the same in design, principles of operation, materials, and performance to the predicate device." MASIMO also fraudulently represented to the FDA that the Pronto met the following accuracy specifications when measuring total hemoglobin:

- **within +/- 1 g/dL** (grams of hemoglobin per deciliter of blood) **of a verified lab result at the first standard deviation** (68% of the time);

- **within +/- 2 g/dL of a verified lab result at the second standard deviation** (95% of the time);
- **within +/- 3 g/dL of a verified lab result at the third standard deviation** (99.3% of the time); and
- **more than +/- 3 g/dL off of a verified lab result at the fourth standard deviation** (the remaining 0.7% of the time).

A "normal" hemoglobin reading in an adult would be between 12 to 16 g/dL. By way of illustration, if an adult's lab-verified hemoglobin level were at 13 g/dL, MASIMO claimed that its Pronto device measurement would be accurate to within 1 g/dL of this measurement (i.e., Pronto would give a reading between 12 g/dL and 14 g/dL) 68% of the time. MASIMO claims that Pronto is accurate to within 2 g/dL of a verified lab result 95% of the time, and accurate to within 3 g/dL of a verified lab result 99.3% of the time.

In reality, the Pronto's performance was nowhere near MASIMO's claimed accuracy specification.

MASIMO also used its FDA approval of the Radical-7 and the Pronto to obtain speedy FDA approval of a new hemoglobin spot checking device, the *Pronto-7*, by fraudulently representing to the FDA that the Pronto-7 was substantially equivalent to the predicate device, the Pronto. This was false because the Pronto-7 did not have a functional pulse oximetry ("SpO2") sensor for rendering an SpO2 measurement, as did the Pronto, and as required by the FDA in order to designate the device as substantially equivalent to the predicate device. MASIMO also fraudulently represented to the FDA that the Pronto-7 met the claimed accuracy specification of the predicate devices, which it did not.

Once MASIMO obtained approval from the FDA to market the Pronto and the Pronto-7, MASIMO rushed the devices to market even though complaints were pouring in from TMs, customers, and attendees at trade shows regarding the wild inaccuracy of the devices when reading SpHb, which was the primary function of the devices. Plaintiffs are informed and believe, based on statements made by MASIMO CEO Joe Kiani, that MASIMO did so because Kiani wanted to be the first company in the market with a non-invasive, spot checking

hemoglobin device, and he was aware that another competitor, OrSense, had a competing device that was awaiting FDA approval.

MASIMO used its reputation as the "gold standard" for *pulse oximetry* measuring devices to convince potential buyers that its *non-invasive hemoglobin* products were of equal quality. Knowing that its products did not work as advertised, MASIMO nonetheless went to great lengths to get these devices into as many physicians' offices and hospitals as possible. MASIMO provided free trials of the Pronto and Pronto-7 to physicians, and encouraged the physicians to seek reimbursement for such uses through fraudulent Medicare charges. Despite numerous and continuing reports concerning wildly inaccurate readings, MASIMO took the "sell at all costs" approach, which included instructing TMs to lie about the accuracy of the devices, manipulating or hiding clinical data to make the devices appear more accurate than they were, instructing TMs to pay physicians under the table to push sales of the devices, and falsely stating that the testing done by the devices was reimbursable under the Child Health and Disability Prevention Program ("CHDP"), a program funded with state and federal taxpayer dollars.

MASIMO was aware that the Pronto and Pronto-7 devices had the potential to cause serious misdiagnoses of patients, which could lead to injury, aggravated illness, or even death, in the case of, for example, a severely anemic patient or an internally bleeding, post-surgical patient who received a "normal" result from one of the devices. MASIMO knew that once it put the Pronto, Pronto-7, and Radical-7 devices in physicians' offices and in hospitals, physicians would use readings from the devices to watch for blood loss, to make patient diagnoses, and to determine treatment such as blood transfusions, iron supplements, and drug dosing. Despite the fact that each device raised serious and repeated questions concerning safety and efficacy during the premarket stage, because MASIMO refused to report known problems truthfully and completely to the FDA, the Pronto and Pronto-7 devices received FDA approval.

From the start, virtually all of MASIMO's TMs who were tasked with selling the original Pronto devices complained of device inaccuracies, and later, provided MASIMO management with "1022 forms" of product malfunctions and continually expressed concerns verbally about the devices. The 1022 forms were internal MASIMO forms used to record customer feedback

regarding complaints, device malfunctions, or product improvement suggestions. At first, MASIMO management made excuses for the accuracy problems, but eventually began to admit problems, at least internally, as complaints of inaccuracies mounted and customers asked to return devices. Instead of pulling the devices until it could fix the problems, MASIMO management continued to invent fanciful excuses for the devices' malfunction and instructed its TMs to use these excuses when faced with physicians who were complaining about the devices. These excuses for device inaccuracies included improper lighting in the examination room, TMs' operating error, ambient and hand temperature, altitude, and cell phone/electrical interference.

All of these excuses were designed to hide the problem, which was that the devices simply did not work. Knowing that the devices did not work, MASIMO failed to fix the devices and failed to report device malfunctions to the FDA. As complaints continued to mount, forcing MASIMO to address the problem in some manner, MASIMO voluntarily recalled the Pronto in mid-2009.

Unfortunately, MASIMO was more concerned with the consequences of having to report this self-imposed recall to the FDA than it was with the consequences of keeping these potentially dangerous devices in the market. MASIMO instructed each TM to return at least one faulty device to at least one physician in their territory in an attempt to justify the company's refusal to notify the FDA of the recall. Without fixing the accuracy problems, MASIMO began selling the Pronto device again approximately eight months later, while waiting for the Pronto-7 to be approved by the FDA.

Virtually every TM MASIMO hired to sell the Pronto and Pronto-7 has complained repeatedly and consistently about the inaccuracy of the devices. TM Heidi Hawkins apparently made the mistake of complaining a bit too vocally in front of several members of MASIMO's upper management at the Pronto-7 launch meeting in July 2010. Plaintiffs are informed and believe that she was promptly placed on a Performance Improvement Plan, was given an impossible sales quota that none of the TMs at MASIMO met, and then was terminated by MASIMO on August 31, 2010, in retaliation for her complaints about the MASIMO's fraudulent

marketing practices and the wild inaccuracy of the devices.

As the months went by and it became clear that MASIMO could not fix the accuracy problems and would not keep the Pronto and Pronto-7 devices off the market until such time as the devices were as accurate as MASIMO was representing to physicians who would use the devices to make health care decisions, Plaintiffs MICHAEL RUHE and VICENTE CATALA were compelled to resign their employment with MASIMO in October 2010, and in doing so, walked away from lucrative employment, into the worst job market of the past 70 years, at great financial and psychological sacrifice for both of them.

JURISDICTION AND VENUE

1. This Court has jurisdiction to hear this action pursuant to 28 U.S.C. section 1331 because this action arises under the laws of the United States, including 15 U.S.C. section 78; 18 U.S.C. section 1514A; and 31 U.S.C. section 3130(h).

2. The claims involved in this action arose in the Central District of California, in that many of the events described in this complaint occurred within this judicial district. Defendant MASIMO owns and operates facilities within this judicial district, and both Plaintiffs' territories included geographical locations within this judicial district.

3. This Court has pendant and supplemental jurisdiction over Plaintiffs' state law tort and statutory claims pursuant to 28 U.S.C. section 1367. Compensatory and punitive damages, attorneys' fees, and costs, as well as injunctive and equitable relief are sought pursuant to both the federal and California provisions providing for such remedies.

PARTIES

4. Plaintiff RUHE is an adult individual residing in San Diego, California.

5. Plaintiff CATALA is an adult individual residing in Los Angeles, California.

6. Plaintiffs are informed and believe and thereupon allege that Defendant MASIMO is, and was at all times relevant herein, a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Irvine, California.

7. Plaintiffs are ignorant of the true names and/or capacities of the defendants sued herein as Does 1 through 100, inclusive, and therefore sue these defendants by such fictitious

names pursuant to Code of Civil Procedure Section 474. Plaintiffs will amend this Complaint to allege their true names and capacities when ascertained. Each fictitiously-named defendant is responsible in some manner for the occurrences alleged herein, and Plaintiffs are entitled to the relief requested herein against each such fictitiously-named defendant.

8. Plaintiffs are informed and believe and thereupon allege that, at all times material herein, each of the specifically named and DOE defendants was the agent of, employee of, and/or working in concert with, his or her co-defendants and was acting within the course and scope of such agency, employment and/or concerted activity. To the extent that certain acts and omissions were perpetrated by certain defendants, the remaining defendant or defendants authorized, confirmed and/or ratified said acts and omissions.

9. Whenever and wherever reference is made in this Complaint to any act by, or failure to act of, a defendant or defendants, such allegations and reference shall also be deemed to mean the acts and failures to act of each defendant acting individually, jointly, and severally, unless stated otherwise.

10. Whenever and wherever reference is made to individuals who are not named as a plaintiff or as defendants in this Complaint but were who employees and/or agents of Defendant MASIMO, such individuals at all relevant times acted on behalf of Defendant MASIMO within the course and scope of their employment and/or agency.

GENERAL ALLEGATIONS

MASIMO's Violations of Federal and State Law

11. MASIMO (NASDAQ: MASI) is a publicly traded global medical technology company headquartered in Irvine, California. MASIMO describes itself in its marketing materials as a company that develops and manufactures innovative non-invasive patient monitoring technologies, including medical devices and a wide array of sensors for the devices.

12. MASIMO develops and manufactures non-invasive technologies including MASIMO SET pulse oximetry, for which MASIMO's devices are considered the "gold standard" in the medical community. The company's technologies also include Rainbow SET Pulse Co-oximetry, and the recently introduced first-and-only FDA-cleared technology that

purports to measure total hemoglobin non-invasively, on a spot check basis. These spot check hemoglobin devices are sold under the product names *Pronto* and *Pronto-7*. MASIMO also markets and sells continuous hemoglobin monitors, including devices such as the *Radical-7*, the *Rad 87*, and the *Rad 57t*.

13. MASIMO used the Radical-7, Rad 87, and Rad 57t devices as "predicate" devices to obtain speedy FDA approval of the Pronto, by claiming that the design of the Pronto was "substantially equivalent" to that of the predicate devices (which shortens the FDA approval process considerably).

14. Specifically, to achieve a ruling from the FDA that the Pronto was substantially equivalent, MASIMO stated to the FDA that the Pronto was "the same in design, principles of operation, materials, and performance to" a MASIMO device called the *RadCheck*. MASIMO had received FDA clearance on the RadCheck following representations by MASIMO that the RadCheck was substantially equivalent to the Radical-7, Rad 87, and Rad 57t.

15. MASIMO also stated to the FDA that the Pronto-7 was the same in all material respects to the Pronto, and as a result, received FDA approval for marketing and sale of the Pronto-7.

16. The following are statutes and regulations setting forth public policies that MASIMO has violated in its marketing and sales of the devices described above, including its insistence that its TMs make false claims to physicians, hospital and clinical administrators, and other device buyers when marketing and selling the devices.

Corporate and Criminal Fraud Accountability Act of 2002 (Sarbanes-Oxley Act), 18 U.S.C. § 1514A

17. Provisions of the Sarbanes-Oxley Act of 2002, Title VIII, Section 806 (Corporate and Criminal Fraud Accountability Act of 2002), Pub. Law 107-204, Title VIII, section 806(a), July 20, 2002, 116 Stat. 802, codified at 18 U.S.C. section 1514A, and its implementing regulations, among other things, prohibit any publicly traded company or "any officer, employee . . . or agent of such company" from taking any action to "discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee" who "provide[s] information

or cause[s] information to be provided . . . regarding any conduct which the employee reasonably believes constitutes a violation of section 1341, 1343, 1344, or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of federal law relating to fraud against shareholders, when the information or assistance is provided to . . . a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct)."

Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, 15 U.S.C. § 78u-6(h) – Protection of Whistleblowers

18. The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Public Law No. 111-203, in section 922, codified in pertinent part at 15 U.S.C. section 78u-6(h), provides anti-retaliation protection for employees who make disclosures that are required or protected under the Sarbanes-Oxley Act and other laws, rules, or regulations under the jurisdiction of the Securities and Exchange Commission.

19. 15 U.S.C. § 78u-6(h)(1)(A) provides in pertinent part that "[n]o employer may discharge, demote, suspend, threaten, harass, directly or indirectly, or in any other manner discriminate against, a whistleblower in the terms and conditions of employment because of any lawful act done by the whistleblower –

> [***]
>
> (iii) in making disclosures that are required or protected under the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7201 et seq.) . . . and any other law, rule, or regulation subject to the jurisdiction of the Commission.

The Federal Mail Fraud Statute, 18 U.S.C. § 1341

20. 18 U.S.C. section 1341 defines the crime of mail fraud under federal law, and provides in pertinent part: "Whoever, having devised or intending to devise any scheme or artifice to defraud . . . for the purpose of executing such scheme or artifice or attempting to do so, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier,

or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter of thing, shall be fined under this title or imprisoned nor more than 20 years, or both. . . ."

The Federal Wire Fraud Statute, 18 U.S.C. § 1343

21. 18 U.S.C. section 1343 defines the crime of wire fraud under federal law, and provides in pertinent part: "Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money . . . by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both."

Federal False Claims Act, 31 U.S.C. § 3729

22. 31 U.S.C. § 3729 (a)(2) states that any person who knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government is liable to the United States Government for civil penalties unless an exception applies. (See 31 U.S.C. § 3729(a)(7).) Under the statute, "knowing" and "knowingly" mean that a person either has actual knowledge, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. (See 31 U.S.C. § 3729(7)(b)(1)-(3).) A "claim" includes any request or demand for money or property, whether pursuant to a contract or otherwise, which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property requested or demanded. (See 31 U.S.C. § 3729 (7)(c).)

California False Claims Act, Cal. Gov. Code § 12651

23. California Government Code section 12651 states that a person who knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or

approved by the State of California shall be liable to the state for three times the amount of damages the state sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each false claim. (See Cal. Gov. Code § 12651(a)(2).) Under the statute, "claim" includes any request or demand for money, property, or services made to any employee, officer, or agent of the state or of any political subdivision, or to any contractor, grantee, or other recipient, whether under contract or not, if any portion of the money, property, or services requested or demanded issued from, or was provided by, the state. (See Cal. Gov. Code § 12650 (b)(1).) Under the California False Claims Act, "knowing" and "knowingly" mean that a person either has actual knowledge, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. (See Cal. Gov. Code § 12650 (2) (A)-(C).) Under the statute, "person" includes any natural person, corporation, firm, association, organization, partnership, limited liability company, business, or trust. (See Cal. Gov. Code § 12650 (b)(5).)

Medicare & Medicaid Patient Protection Act, 42 U.S.C. § 1320

24. 42 U.S.C. section 1320 states that whoever knowingly and willfully makes or causes to be made:

- any false statement or representation of a material fact,
- in any application for any benefit or payment under a federal health care program, or
- at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

shall, in the case of such a statement, representation, concealment, failure or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony, and upon conviction thereof, fined not more than $25,000 or imprisoned for not more than five years or both. Or, in the case of such statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, such person shall be guilty of a misdemeanor and upon

conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both. (See 42 U.S.C. §1320 (a)-7(B).) "Federal health care program" means any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government. (See 42 U.S.C. §1320 (f)(1).)

25. 42 U.S.C. section 1320 states that whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. (See 42 U.S.C. §1320 (2)(B).)

Conspiracy to Commit Offense or to Defraud United States, 18 U.S.C. § 371

26. 18 U.S.C. section 371 defines the crime of conspiracy to commit an offense against or to defraud the United States, and provides in pertinent part: "If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. § 1320d-6

27. 42 U.S.C. section 1320d-6 provides for various civil and criminal penalties for "covered entities" who violate HIPAA, or for others who "aid and abet" or "conspire" to violate HIPAA by, among other things, disclosing private health information without a patient's authorization.

California Confidentiality of Medical Information Act, Cal. Civ. Code §56.10

28. California Civil Code section 56.10, subdivision (d), provides in pertinent part that, absent consent of a patient, a provider of health care or a corporation shall not

"intentionally share . . . or otherwise use medical information for a purpose not necessary to provide health care services to the patient."

29. California Civil Code section 56.10, subdivision (e), provides in pertinent part that, absent consent of a patient, a corporation shall not further disclose medical information regarding a patient to a person or entity that is not engaged in providing direct health care services to the patient.

California Constitution, Article 1, Section 1

30. Article 1, Section 1 of the California Constitution provides that all people have a right to privacy, among other inalienable rights. The disclosure of a person's private medical information without that person's consent constitutes a violation of this constitutional right to privacy.

California Business & Professions Code section 17500

31. California Business & Professions Code section 17500 provides that it is unlawful for any corporation, with the intent to sell any product or service, to make any untrue or misleading statement about the product or service, with actual or constructive knowledge of the untrue or misleading nature of the statement concerning the product or service.

California Business & Professions Code section 17200

32. California Business & Professions Code section 17200 provides that unfair competition shall mean any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by Section 17500, *et seq.*, of the Business & Professions Code. Section 17203 of the Business & Professions Code provides that a court of competent jurisdiction may enjoin any conduct constituting unfair competition under Section 17200.

California Health & Safety Code sections 119400 and 119402

33. California Health & Safety Code section 119402 provides in pertinent part that a pharmaceutical company shall adopt a Comprehensive Compliance Program ("CCP") in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human

Services Office of Inspector General, and shall update its CCP within six months of any revision to the April 2003 publication. Each CCP must include policies for compliance with the Pharmaceutical Research and Manufacturers of America's "Code of Interactions with Health Care Professionals," dated July 1, 2002, and shall make conforming changes to its CCP within six months of the date of any revision to the July 1, 2002 publication.

34. California Health & Safety Code section 119400, subdivision (c) defines a "pharmaceutical company" as an entity that, among other things, is engaged in the production, marketing, labeling, sale, or distribution of "dangerous drugs." California Health & Safety Code section 119400, subdivision (a), includes in the definition of "dangerous drug" any "drug or device that, pursuant to federal or state law, may be dispensed only by prescription . . . ."

35. MASIMO's aforementioned hemoglobin measuring devices, including the Pronto and Pronto-7 and predicate devices, received FDA approval as devices that may only be administered by a prescription.

Pertinent FDA Regulations Applicable to MASIMO

36. 21 CFR section 803 states that manufacturers must report serious injuries that a medical device may have caused or contributed to, and must report when a device has malfunctioned and would be likely to cause serious injury if the malfunction reoccurred. (See 21 CFR 803.1.) A manufacturer is deemed to be "aware" of an event when any employee acquires information that reasonably suggests a reportable adverse event has occurred. (See 21 CFR 803.3(2).)

37. 21 CFR section 806 states that manufacturers are required to report any remedial action other than routine maintenance or servicing of a device where such action is necessary to prevent reoccurrence of a reportable event. (See 21 CFR 806.1(a)(2).)

38. 21 CFR section 814 governs the regulations that pertain to a premarket notification 510(k), a filing with the FDA that is needed before a device can be approved by the FDA. A premarket notification 510(k) filing requires proof that the new device is "substantially equivalent" to another legally marketed device in the United States that already has FDA approval (known as the "predicate" device). "Substantial equivalence" means the new device

has the same intended use as the predicate and is at least as safe and effective as the predicate. A device cannot be "substantially equivalent" if it raises new questions in regard to safety and effectiveness." (See 21 CFR 807.92(a)(3).)

39. 21 CFR section 820 states that manufacturers shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured. Current good manufacturing practice ("CGMP") requirements are set forth in this section, and govern the methods used in, and the facilities and controls used for the manufacture of, all finished devices intended for human use. Such requirements are intended to ensure that finished devices are safe, effective, and in compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. A requirement is deemed to be "appropriate" if non-implementation could reasonably be expected to result in the product not meeting specified requirements or the manufacturer not taking corrective action. (See 21 CFR 820.1(3).) Each manufacturer is required to maintain files of complaints received and to maintain procedures for receiving and reviewing complaints. Any complaint involving the possible failure of a device to meet any of its specifications should be reviewed, investigated, and reported to the FDA if necessary. (See 21 CFR 820.198.)

40. 45 CFR section 164, *et seq.*, provides extensive regulations concerning the protection of private health information of patients. 45 CFR section 164.508(a) provides that any disclosure of private health information requires an authorization by the patient or patient's representative, except as otherwise provided by law.

PLAINTIFFS' EMPLOYMENT WITH MASIMO AND THEIR OBJECTIONS TO MASIMO'S UNLAWFUL AND DECEPTIVE ACTIVITY

41. On December 8, 2008, Plaintiff RUHE was hired by MASIMO as a TM in MASIMO's Physician Office market. Plaintiff RUHE's territory included a subset of southern California, ranging north/south from San Diego to Orange County, and east to San Bernardino and Riverside Counties.

42. In Orange County, some of Plaintiff RUHE's larger customers and potential customers for MASIMO's defective devices included such medical practice groups as *Pacific*

Pediatrics, *Talbert Medical Group*, *Gateway Medical Group*, and *Westminster Medical Group*.

43. Some of Plaintiff RUHE's larger customers and prospective customers outside of Orange County included *Loma Linda University Medical Center* in Loma Linda, and *Scripps Health*, *Balboa Nephrology*, and the *Naval Medical Center San Diego* in San Diego.

44. In January 2009, in a Limited Market Release, MASIMO launched the Pronto device, which MASIMO claimed could be used to spot check total hemoglobin (SpHb), oxygen saturation (SpO2), pulse rate, and perfusion index.

45. The term "Limited Market Release," as used by MASIMO, meant a product release in which the company attends trade shows and markets the product, but does not yet have a fully developed, fully funded marketing procedure in place for the product. During the Pronto's Limited Market Release, MASIMO asked its customers to assess the Pronto device during the early release stage, in exchange for a promise by MASIMO to "take care of" these physicians later on, with software and hardware upgrades either at a substantial discount, or in some cases, for free. During this Limited Market Release, MASIMO charged up to $6,000.00 per each Pronto device.

46. As TMs in the Physician Office market, Plaintiff RUHE was the first TM hired to sell MASIMO's new Pronto device when it was released.

47. TMs who sold the Pronto were instructed by MASIMO management to tell physicians who asked about the accuracy of the device that it was within +/-1 g/dL of a verified lab result. In some of MASIMO's training and other materials given to TMs, MASIMO provided additional accuracy specifications for the device, which stated that hemoglobin measurements would be within +/-1 g/dL of a verified lab result 68% of the time (1st standard deviation), within +/-2 g/dL of a verified lab result 95% of the time (2nd standard deviation), and within +/-3 g/dL of a verified lab result 99.3% of the time (3rd standard deviation). The remaining 0.7% of the time included anything more than +/-3 g/dL off of a verified lab result (4th standard deviation). These statistics were MASIMO's official, stated accuracy specifications that MASIMO has used to market and sell the Pronto and Pronto-7 devices, as well as the Radical-7 device.

48. Plaintiff RUHE and the other TMs were repeatedly instructed that when they sold the Pronto devices, they should use MASIMO's established reputation as the "gold standard" in pulse oximetry measurement to lend credence to MASIMO's new, non-invasive, hemoglobin measuring devices. Furthermore, when discussing the Pronto device, TMs were instructed to use the data from MASIMO's Radical-7 device (a predicate device to the Pronto and Pronto-7, the FDA clearance for which Plaintiffs are informed and believe to have been based on a questionable, cherry-picked clinical study).

49. In January 2009, the Pronto units given to TMs as demo units frequently produced measurements that were equal to or greater than +/-3 g/dL off of the verified lab values determined by a blood draw from the patient (the traditional, proven method of measuring hemoglobin). These frequent, significant inaccuracies from the Pronto were a serious problem, because readings that are more than 3 g/dL off of the accurate value are outside the 3rd standard deviation in the claimed accuracy specification, and under the claimed accuracy specification, errors of this magnitude were supposed to happen only than 0.7% of the time. MASIMO TMs dutifully reported these inaccuracies to MASIMO management. Instead of taking these reports seriously, MASIMO's management blamed the inaccuracies on "TM error," and crafted other convenient, often fanciful, sometimes bizarre, excuses for why the devices were not functioning properly. These excuses included blaming device malfunctions on ambient lighting in the room, ambient and hand temperature, electrical or cell phone interference, or altitude.

50. During this time, Plaintiff RUHE discussed his concerns regarding inaccuracy with his Regional Manager, John Birkle, who stated, "It really doesn't matter, because it's not for us to decide. We still have to sell it."

51. Plaintiffs are informed and believe and thereupon allege that when accuracy problems began to mount for the noninvasive SpHb testing product line, MASIMO CEO Joe Kiani personally headed up the product review meetings for the Radical-7, Pronto, and Pronto-7, and had full knowledge of all of the problems with device inaccuracies, but continued to insist that the company sell the devices to health care providers anyway, because he wanted to be first to market.

52. In mid-January 2009, MASIMO management, including Birkle, Gary Marston (Head of Marketing), and Kevin Hammond (V.P. of Sales in the Physician Office market), began instructing TMs to "spin" the standard deviation explanation to physicians by claiming that any confirmed inaccuracies were simply rare outliers, and that such inaccuracies did not take the device out of the company's claimed accuracy specification.

53. TMs were instructed by management to keep conversations brief when speaking with physicians during sales calls regarding accuracy problems. Employees were encouraged to discuss the 1st standard deviation openly (i.e., to emphasize that the device was accurate to within 1 g/dL of the lab value), but not necessarily the 2nd or 3rd standard deviations if it could be avoided. When management traveled in the field with the TMs and were asked by physicians about accuracy, they would often give the incomplete answer "plus or minus 1 g/dL," neglecting to acknowledge the 2nd and 3rd standard deviations at all. Management also instructed TMs to tell physicians that "the accuracy of the Pronto was comparable to the Hemocue [the industry leader in invasive hemoglobin monitoring, requiring a needle stick] or even better."

54. In March 2009, a MASIMO TM reported that the Pronto gave grossly inaccurate readings in high altitude locations. MASIMO, however, instructed its TMs to tell clinicians that altitude did not affect the Pronto's ability to produce an accurate reading. Instead, MASIMO continued falsely blaming device inaccuracies on operator error and accusing TMs of misplacing Pronto sensors on patients' fingers.

55. On March 23, 2009, MASIMO hired Plaintiff CATALA as a TM for the greater Los Angeles area, north to San Luis Obispo, and the southern Central Valley area markets. Plaintiff CATALA's official title was "Territory Manager," and later changed to "Territory Hemoglobin Specialist," along with every other TM in the Physician Office market. His job responsibilities were identical to those of Plaintiff RUHE and the other TMs.

56. In or about April 2009, during Plaintiff CATALA's intial job training meeting, a training meeting attended by the entire Physician Office sales force, he and many other TMs were SpHb tested using the Pronto and observed that the results produced by the device were drastically different from lab results obtained through conventional invasive blood testing in

close temporal proximity to the Pronto results. The Pronto results for Plaintiff CATALA and two other TMs were greater than 4 g/dL off their respective lab values, results that should occur only 0.7% of the time. MASIMO blamed Plaintiff CATALA's "body chemistry" for the inaccurate results. Paul Jansen (MASIMO's Executive Vice President of Marketing and Clinical Development) and Marston stated that they "had never seen that kind of behavior with the device," and Marston joked that Plaintiff CATALA must be a "freak of nature" because the device was not working on him.

57. At this same meeting, one of the TMs stated that the Pronto was producing inaccurate results, especially on medium to darker skin tones. Jansen replied, "We have NEVER seen inaccuracies like this before," and then blamed the overhead projector and cell phone interference in the room for the inaccurate results (a strange claim to make for a device supposedly designed to operate in environments filled with other electrical equipment and medical devices).

58. In early April 2009, Joe Kiani (MASIMO's CEO, Co-founder, and Chairman of the Board) spent a day in the field with Plaintiff RUHE as he made sales calls on physicians' offices. CEO Kiani saw firsthand that the Pronto was inaccurate during in-office demonstrations. In one Orange County physician's office, the office manager (who stated that she had been medically confirmed as chronically anemic) was tested using the Pronto device, which produced a "false negative" result, where her hemoglobin reading incorrectly indicated that she was not anemic. CEO Kiani invited her back to MASIMO's corporate office for additional testing and research and explained that she was an ideal subject because she was young and anemic, but otherwise healthy. He said subjects with that profile can be difficult to find, and that sometimes anemic status in research subjects must be simulated through hemodilution. After leaving the office, CEO Kiani asked Plaintiff RUHE how often he experienced such extreme inaccuracies. Plaintiff RUHE responded, "unfortunately, a few times a day." CEO Kiani asked RUHE how many returns he expected to receive based on performance issues. RUHE told Kiani that based solely on the complaints he had received thus far, he estimated at least one-third and possibly one-half of Pronto devices sold could be returned

due to concerns about poor performance.

59. During the same field travel day, CEO Kiani discussed device accuracy with Plaintiff RUHE. He told Plaintiff that he should seek out customers who want to be "partners of ours." CEO Kiani said that customers need to recognize that the Pronto is not yet perfect and suggested that Plaintiff RUHE make it clear to physicians that MASIMO is seeking users who will provide important feedback necessary for MASIMO to fine-tune and further develop the Pronto.

60. Around April 2009, inaccurate Pronto SpHb readings continued to accrue at an alarming rate, and MASIMO's executive management became more defensive. Instead of adressing the accuracy problems in a responsible way, management suggested that TMs "bag fingers" (place a black bag over a patient's finger to shield it from surrounding light). When complaints of inaccuracy arose, management would ask, "Did you remember to use a black bag?" Large quantities of black bags were shipped out to TMs to be distributed among customers and prospects for use while testing the devices. More than a year later, Gary Marston confirmed in separate "off the record" conversations with two TMs that, as far as he could tell by looking at the data, there was no clinical significance to the black bag, in terms of how it affected an SpHb reading.

61. Also around April 2009, a TM reported to Birkle that one physician did not want to purchase the Pronto because it was overpriced. Birkle suggested that the TM "pay him" (the physician) under the table to push the sale. Birkle then chastised the TM for pointing out that such behavior was unethical and illegal.

62. In approximately April 2009, Birkle also told Plaintiff RUHE that he should "do whatever it takes" to make a sale, including doing favors for or offering "spiffs" to distributor representatives. The implication to Plaintiff RUHE was clear that he was to offer distributors and their sales representatives cash bonuses under the table in exchange for sales and/or leads that could ultimately turn into sales.

63. In response to numerous complaints of inaccuracies from the field, MASIMO's co-founder, Mohammed Diab, several MASIMO engineers, and two MASIMO corporate

Product Managers, Jay Hachey and Loree Boldman, met with Plaintiff RUHE at MASIMO headquarters in Irvine. The purpose of the meeting was to watch Plaintiff RUHE demonstrate the inaccuracies he was experiencing and to show them his testing technique so that they could ensure that his technique was not causing the accuracy problems he was reporting. Using his field demo Pronto device, Plaintiff RUHE ran a number of SpHb tests on most or all of the attendees at the meeting to demonstrate how non-reproducible Pronto results were. The device produced wild swings in SpHb measurements on all of the test subjects, and included numerous variations of +/-3 g/dL, or greater, from the same subjects from tests taken mere minutes apart. The MASIMO corporate attendees were largely silent during this meeting, except when Diab told Hachey to plug Plaintiff RUHE's Pronto sensor into a MASIMO computer to record several additional readings from attendees and from other MASIMO passersby. These results, too, were wildly inaccurate. When Plaintiff RUHE and Hachey spoke after the meeting, Plaintiff RUHE asked whether Hachey thought that Diab and the engineers had seen how poorly the device was performing, because Diab had been so nonchalant during the meeting. Hachey replied, "Yeah, they sure did. They just weren't going to admit that." After this conversation, Plaintiff RUHE never heard another word about it from Diab, Hachey, or anyone else at MASIMO.

64. In May 2009, Plaintiff RUHE conducted device evaluations in three physicians' offices and compared the results of the Pronto and Radical-7 SpHb measurements against conventionally obtained lab values. The mean variances rendered by the Pronto and Radical-7 when compared to actual lab values were greater than +/-2 g/dL at all three offices. Per instructions from Marston, Plaintiff RUHE saved these results to an SD flash card and sent them via FedEx to Marston.

65. Also in May 2009, CEO Kiani attended the PriMed West 2009 Conference and Exhibition, and after seeing with his own eyes that the Pronto was returning wildly inaccurate readings and that doctors were laughing at the device, left the showroom floor in embarrassment. Later, while sitting at the hotel lounge, Marston, Jansen, and Hammond admitted to Plaintiffs RUHE and CATALA that there were accuracy concerns about the Pronto at the upper levels of MASIMO management. Jansen called MASIMO's headquarters and asked for a team of

engineers to come to the PriMed show the following day to witness the inaccuracies.

66. As the records of inaccuracies mounted, Plaintiffs RUHE and CATALA voiced their concerns to Birkle, Marston, and Hammond. Birkle, Marston, and Hammond told Plaintiffs RUHE and CATALA to "spin" the standard deviation explanation by telling doctors that any obvious inaccuracies were simply rare, statistical outliers, and that the majority of results were accurate.

67. During this time, Plaintiffs and the other TMs were also instructed to talk about the device being accurate to within 1 g/dL, and not to talk about results outside of this 1st standard deviation unless in response to a specific complaint about accuracy.

68. In July 2009, two cases at the Intermountain Medical Center in Colorado produced SpHb readings which were +/-6 g/dL off of the actual lab values. Gary Clawson, (MASIMO's director of Clinical and Professional Development) admitted that MASIMO had no idea why Pronto produced major outliers such as these.

69. In July 2009, MASIMO finally recalled the Pronto device following the disasterous May 2009 PriMed West show.

70. In July 2009, MASIMO held a division-wide Physician Office market meeting in Irvine. During this meeting, MASIMO's Executive Vice President of Marketing, Paul Jansen, admitted to the TMs in the division that inaccuracies that are beyond +/-2 g/dL of SpHb (on the Pronto) "will kill you in a spot check device" in terms of physician acceptance, but are more acceptable with a continuous monitor such as the Radical-7. This is because, according to Jansen, the "real clinical value" in a continuous monitor is the "trending" line (up, down, or stable) of a patient's hemoglobin value over the course of time. This statement, that the "trend" was what mattered on continuous measurement devices, was contrary to the accuracy spec of the Radical-7, which was the same as, and formed the basis of FDA approval of, the Pronto and Pronto-7.

71. As a result of MASIMO's recall of the Pronto in July 2009, Plaintiffs and the other TMs suddenly had no product to sell. MASIMO transitioned its Pronto TMs into the acute care setting and asked them to sell the Radical-7. Because the Radical-7 had similar inaccuracy

issues to those experienced with the Pronto, Plaintiffs RUHE and CATALA were instructed to focus on the "trending" aspect of the Radical-7, instead of the actual SpHb number the device produced, when making sales calls. Plaintiffs and other TMs were also instructed to return recalled Pronto devices to at least one physician in each of their territories, and to ask the physicians to keep the devices in their offices but not to rely on them for making diagnostic decisions, so that MASIMO would not have to report the voluntary recall to the FDA.

72. Around November 2009, Plaintiff RUHE was selected by Birkle to represent the western region on MASIMO's "Continuous SpHb Core Team" (CSCT). This team comprised clinical specialists and TMs from various divisions and regions throughout the country. The team assembled monthly via teleconference. Dan Draper (Marketing V.P.) was the host and key facilitator. One of the main purposes of the CSCT was to "generate graphic reports to demonstrate the power of the SpHb trend graph to our prospective customers." During scheduled teleconferences, the CSCT members would grapple with the more difficult and urgent cases and questions from the field, many of which went unanswered because there were no explanations other than that the devices were simply failing. Within a few months of Plaintiff RUHE joining the team, the CSCT was quietly disbanded. Plaintiff RUHE was never informed why this occurred.

73. In December 2009, Plaintiff RUHE was at a major university medical center, conducting general follow-up regarding the Radical-7. A highly respected physician who was a professor at the university stated to Plaintiff RUHE that he (the physician) should be "put on the MASIMO payroll for acting as damage control for the [Radical-7] device," because there were so many questions about apparent inaccuracies during operating room cases. This physician then explained to Plaintiff RUHE how he often had to spin the "trending" explanation to his peers in order to explain away the devices' inaccuracies. This physician also stated that he didn't believe the Radical-7 was accurate on patients with jaundice, and that there was no acknowledgement in any of MASIMO's literature as to limitations on specific patient populations, such as those suffering from jaundice. Plaintiff RUHE reported this physician's concerns to Marston publicly, during a national, division-wide conference call. Marston promised to get back to Plaintiff

RUHE about this, but then never did.

74. During the time that the Pronto TMs were assigned to sell the Radical-7, numerous customers raised concerns about the accuracy of the Radical-7's continuous SpHb measurement function, upon which the Pronto and Pronto-7 accuracy specs were based. MASIMO management responded to such concerns with a new internal marketing slogan: "Trend is your friend," meaning that physicians should focus not on the numerical SpHb reading given by the device (because it could be quite inaccurate far more frequently than the accuracy spec indicated), but on whether the SpHb level was going up, down, or staying level over time. TMs were coached to use this slogan and remind customers to essentially disregard the actual SpHb reading that appeared on the Radical-7 monitor, but to instead focus on the SpHb trend over the course of a continuous measurement. This marketing strategy was not consistent with what MASIMO was representing in its Radical-7 accuracy specification. Although Plaintiffs only spent approximately four months selling the Radical-7, they observed enough accuracy problems during that time to raise serious doubts in their minds as to the claimed accuracy specification of this predicate device to the Pronto and Pronto-7 devices that Plaintiffs had been hired to sell.

75. In Q1 2010, MASIMO pulled Plaintiffs and the other Pronto TMs off of the Radical-7 sales project and instead paid them their full salary and guarantees of approximately $11,000.00 per month to locate and retain physicians to act as Principal Investigators on Independent Review Boards for MASIMO. This constituted a significant outlay of cash for MASIMO to pay all of its TMs, who were device salespeople and not trained and qualified clinical research associates. Most of the TMs who were paid this money during this quarter did not retain a single physician as a Principal Investigator, and yet, oddly, MASIMO management did not seem to care. Plaintiffs are informed and believe and thereupon allege that MASIMO retained its Pronto TMs as "window dressing" for Wall Street, so that it could provide false assurances to investors and Wall Street analysts that, despite the looming expiration of MASIMO's patents on its pulse oximetry devices, it had its "next big thing" in its spot checking hemoglobin devices.